MAY 1 2 2000

K001208

2 SPECIAL 510(k): DEVICE MODIFICATION SUMMARY

This Special 510(k) is being submitted by

Respironics California, Inc.
1261 Liberty Way
Vista, CA 92083
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The contact person for this submittal is:

Kathy Moore, Manager of Compliance & Regulatory Affairs
Phone: 760-734-3221

This summary was prepared on April 11, 2000.

This special 510(k) is for the Graphics modification of the Esprit™ critical care ventilator, product code (21CFR 868.5895, 73CBK). The legally marketed predicate device is the 7200 ventilator with the Waveform Display Option 60. The 7200 ventilator is currently used in both invasive and non-invasive applications. The unmodified legally marketed Esprit™ critical care ventilator has been cleared under 510(k) number K981072. The current Esprit™ offers a small pressure versus time waveform that is presented in several screens of the display. The Graphics modification will allow for pressure, flow and volume waveforms along with pressure-volume and flow-volume loops.

The specific features of the Graphics modification include:

- A waveforms screen which will display Pressure versus Time, Flow versus Time, and Volume versus Time waveforms.
- A loops screen which will display Flow versus Volume and Volume versus Pressure loops.
- Adjustable time scales
- A freeze function that suspends subsequent plotting of graphical data.
- A cursor function that allow for the display of discrete data points.
- A Re-plot/Scrolling function.
- Automatic and manual re-scaling.

The Esprit™ ventilator with the Graphics modification is intended to be marketed worldwide, as is the currently marketed Esprit™ ventilator, to address the needs of low and moderate acuity subacute facilities in the US, surgical recovery units in hospitals, in

ICU applications, in stand alone surgery centers in undeveloped and emerging nation, rest-of-world (ROW) markets. No medical claims are made regarding the ventilator.

The Esprit™ ventilator with Graphics option is intended for use by qualified medical personnel in providing continuous or intermittent ventilatory support for adult and pediatric patients as prescribed by a physician. The Esprit™ ventilator is intended for use in either invasive or non-invasive applications. Refer to **Appendix A - Statement of Indications for Use.**

The Graphics modification of the Esprit™ ventilator does not employ any new technological characteristics as found in the legally marketed predicate device (7200 ventilator with Waveform Display Option 60).

The intended use of the Esprit™ ventilator, as described in its labeling, has not changed as a result of the Graphics option.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2000

Ms. Kathy Moore
Respironics California, Inc.
1261 Liberty Way
Vista, CA 92083

Re: K001208
Trade Name: ESPIRT
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: April 13, 2000
Received: April 14, 2000

Dear Ms. Moore:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and Radiological
Health

Enclosure

510(k) Number (if known): K001208

Device Name: Esprit™ ventilator (with Graphics Option)

Indications for Use:

The Esprit™ ventilator with Graphics option is intended for use by qualified medical personnel in providing continuous or intermittent ventilatory support for adult and pediatric patients as prescribed by a physician. The Esprit™ ventilator is intended for use in either invasive or non-invasive applications.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number

Prescription Use ✓ or Over-The-Counter Use _____